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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,586	12/29/2003	Martin R. Willard	1001.1714101	8579

28075 7590 10/12/2005

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EXAMINER	
BRUENJES, CHRISTOPHER P	
ART UNIT	**PAPER NUMBER**
1772	

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/750,586	WILLARD ET AL.	
	Examiner	Art Unit	
	Christopher P. Bruenjes	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040326, 20040415*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, drawn to a catheter, classified in class 428, subclass 36.9.

II. Claims 26-27, drawn to a method of making a catheter, classified in class 264, subclass 500.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the claimed product can be made by another and materially different process such as co-injection molding the polyoxymethylene and polyether polyester with the amount of each differing throughout the amount provided of each material from the initial material that enters the mold to the final material

that enters the mold, which is in the shape of a tube, followed by allowing the material to cool and set.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with David Crompton on August 17, 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the polymer blend shaft". There is insufficient antecedent basis for this limitation in the claim. It is suggested to add a limitation in claims 1 after "comprising:" and before "a proximal" reading "a polymer blend shaft comprising".

Claim 3 is rejected for being dependent on claim 2 and includes the same limitation as rejected in claim 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the

> differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itou et al (EP 1 068 876 A2) in view of Utsumi et al (USPN 5,258,160).

Regarding claims 1, 24, and 25, Itou et al teach a catheter shaft comprising a proximal portion, a distal portion, and an intermediate portion between the proximal and distal portions (col.3, l.23-27). A first resin layer is arranged in a first region of the tubular member and consists of a first resin material disposed in a dense spiral or mesh and a second resin material disposed in a sparse spiral or mesh, and a second resin layer is arranged in a second region of the tubular member and consists of the second resin material disposed in a dense spiral

or mesh and the first resin material disposed in a sparse spiral or mesh. The intermediate region between the first and second regions consists of the first resin material disposed in a spiral or mesh of a disposing density intermediate between the disposing densities in the first and second regions and the second resin material disposed in a spiral or mesh in a disposing density intermediate between the disposing densities in the first and second regions (col.3, l.27-45). The first region represents the proximal portion and the second region represents the distal portion of the catheter shaft (col.3, l.46-50). The first resin material has a flexural rigidity higher than that of the second resin material (col.4, l.23-25). Therefore, Itou et al teach that the proximal portion is predominantly a more rigid resin and the distal portion is predominantly a less rigid resin. After the spiral shaped material is disposed in the shaft the first and second materials are melted and mixed or fused and then solidified (col.4, l.26-33). Therefore, the layer is a blend of the two materials. The proximal portion has a concentration of the more rigid material within the claimed range of 80 to 95% by weight and a concentration of the less rigid material within the claimed range of 5 to 20% (col.10, l.32-37). The distal portion has a concentration of the more rigid material within the claimed

range of 5 to 20% and a concentration of the less rigid material within the claimed range of 80 to 95% (col.10, l.38-43). The intermediate portion obviously has a concentration of the more rigid material within the claimed range of 20 and 50% and a concentration of the less rigid material within the claimed range of 50 to 80%, since the concentration of the two materials are values between the values of the concentration of the respective materials in the proximal and distal portions. The materials chosen for the formation of the blend material are a combination of at least two material chosen form a group that includes polyoxymethylene and polyester elastomers (col.9, l.13-30), in which the polyester elastomers is described as a polyether polyester (col.11, l.46-53). Regarding claims 2, 8, 13 and 20, the catheter shaft further comprises an inner polytetrafluoroethylene tubular member disposed within the polymer blend shaft (col.11, l.19-31 as the base tube or col.12, l.24-33 as the low friction layer). Regarding claims 3, 9, and 15, the catheter shaft further comprises a braided metallic support member disposed between the inner polytetrafluoroethylene tubular member and the polymer blend shaft (col.11, l.57 - col.12, l.11). Regarding claims 5-6 and 17-18, the catheter shaft further comprises a distal tip coupled to the distal portion of the catheter shaft made completely from

the less rigid material (col.3, l.19-22). Regarding claim 7, the catheter shaft the polymer blend in which the more rigid material forming the majority of the proximal portion has a flexural modulus between 8,000 and 25,000 kg/cm^2, which overlaps the claimed range of 210 to 380ksi for the proximal portion, and the less rigid material forming the majority of the distal portion has a flexural modulus between 100 and 4000 kg/cm^2, which overlaps the claimed range of less than 30ksi (col.9, l.44-57). The intermediate portion obviously has a flexural modulus that falls within the claimed range of 30 to 90ksi, because the intermediate portion contains a substantial amount of both of the materials and therefore, would have a flexural modulus intermediate of the flexural modulus for the proximal and distal portions. Regarding claim 11, see the teaching for claim 1 above. Regarding claim 12, the claim is a generalized recitation of claim 3 already taught above. Regarding claim 14 and 21, the inner layer comprises polyethylene (col.11, l.19-31 as the base tube or col.12, l.24-33 as the low friction layer). Regarding claim 16, the support member includes a coil (col.12, l.4-6). Regarding claim 19, Itou et al teach that the catheter shaft taught is used in the manufacture of a balloon catheter (col.23, l.21-32) having the limitations of claim 2 shown above, and would necessarily have a balloon coupled to the distal

portion of the outer tubular member in order to be considered a balloon catheter. Regarding claim 22, the inner tubular member defines a guidewire lumen extending therethrough (col.12, l.41-47). Regarding claim 23, the balloon catheter obviously contains an inflation lumen between the inner tubular member and outer tubular member because the catheter is a balloon catheter and balloon catheters require an inflation lumen.

Itou et al fail to explicitly teach that polyoxymethylene is chosen as the more rigid material and that the polyether polyester is chosen as the less rigid material. However, Utsumi et al teach that in the art of forming catheters having a varying rigidity longitudinally throughout the catheter, polyester elastomer such as polyether polyester taught by Itou et al is commonly used as a the flexible material, and polyoxymethylene taught by Itou et al is commonly used as a rigid material. One of ordinary skill in the art would have recognized that Itou et al teach that polyoxymethylene and polyether polyester are materials that are used in the formation of the polymer blend layer of the catheter of Itou et al and that polyoxymethylene is a known torque transmitting material for formation of rigidity varying catheters and that polyether polyester is a known flexible material for formation of rigidity varying catheters, as taught by Utsumi et al.

Therefore, it would have been obvious to select polyoxymethylene as the more rigid material of Itou et al and polyether polyester as the less rigid material of Itou et al, since polyoxymethylene is known in the art as a commonly used rigid material for this particular purpose and polyether polyester is known in the art as a commonly used flexible material for this particular purpose, as taught by Utsumi et al, and it would be obvious to select materials form the group taught in Itou et al to produce the catheter shaft of Itou et al.

Regarding claims 4 and 10, Itou et al teach that the proximal portion, intermediate portion, and distal portion define a total shaft length and that the lengths of the individual regions depend on the shape, kind, etc., of the catheter, and are not particularly limited (col.26, l.10-12). Itou et al goes on to teach the lengths of the regions with regard to one particular type of catheter, in which the proximal portion (formed of regions 22 and 23 combined) is 580 to 1150 mm, the intermediate portion (region 24) is 20 to 80mm, and the distal portion (region 25) is 5 to 20mm (col.26, l.12-20). Note the region 26 is the distal tip. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select the lengths of the individual

portions within the claimed ranges, since the lengths would be determined based on the size, kind, type, etc., of the catheter and based on the fact that the cited example teaches length ranges that overlap with the claimed ranges.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Itou et al (USPN 6,511,462); Gale (USPN 4,243,580) teaches that polyether polyester and polyoxymethylene are compatible and blendable and that polyether polyester has a lower flexural modulus that polyoxymethylene; Seymour et al (USPN 4,904,748) teach that polyether polyester has a low flexural modulus that is within the range of desired flexural modulus required for the flexible material of Itou et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB CPB
September 27, 2005

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

9/28/05